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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,454	08/04/2005	Alexei Slesarev	FID001 US	8305

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,454	SLESAREV ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-21 and 24-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: NOTICE TO COMPLY; SEQUENCE COMPARISON 1 OF 6/12/07; SEQUENCE COMPARISON 2 OF 6/12/07; SEQUENCE COMPARISON 3 OF 6/12/07; SEQUENCE COMPARISON 4 OF 6/12/07; ACCESSION DATA 1 OF 6/12/07.

DETAILED ACTION

Applicant's response to restriction requirement and amendment of 5/11/07 is entered.

Claims 1-31 are pending.

Election/Restrictions

Applicant's election without traverse of Claims 4-6 and 22-23, and the specific sequence of SEQ ID NO: 1692 in the reply filed on 5/11/07 is acknowledged.

Claims 1-3, 7-21, and 24-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/11/07.

Claims 4-6 and 22-23 are presently considered with respect to the elected invention, SEQ ID NO: 1692.

Note: SEQ ID NOS not properly reflective of elected protein

It is noted that the Examiner ordered a search on SEQ ID NO 1692, however, when the results were returned to the Examiner, it was found that SEQ ID NO: 1692 as provided in the electronic copy of sequence listing was actually a short nucleotide sequence, and not the protein of SEQ ID NO: 1692 provided in the specification. Further research identified SEQ ID NO: 1689 of the electronic copy to actually be SEQ ID NO: 1692 of the specification. Hence, a new search was conducted on such SEQ ID NO: 1689, as the specification is controlling, and it is apparent that Applicant actually provided an incorrect electronic copy.

Specification

Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically the application fails to comply with CFR 1.821(d), which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

The specification discloses nucleotide and amino acid sequences on the pages 37+ of the specification. However, these sequences do not match the digital copy provided to the office.

For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures, by providing a proper electronic copy of the SEQ ID NOS and a proper statement that the electronic copy is the same as the paper copy.

Claim Objections

Claims 4-6 and 23 are objected to containing non-elected subject matter, i.e., the various proteins of the various SEQ ID NOS, as well as the various nucleic acids and antibodies to the proteins (Claim 23 only).

Claims 22-23 are objected to for being dependent from withdrawn claims, as well as encompassing the various SEQ ID NOS of proteins and antibodies and nucleic acids (Claim 23 only).

It is recommended that Applicant limit their claims to the protein elected and remove dependencies from non-elected inventions.

Claim Rejections - 35 USC § 101 and 35 USC 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-6 and 22-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claimed inventions are required to meet the requirements of utility under patent law. Patent law requires the claimed invention be supported by a credible, specific, and substantial use.

Specific utilities are those utilities that are specific to the protein and not general to a class of proteins, e.g., as probe or a marker or treatment for an unspecified disease.

Substantial utilities are those that are "real world" and do not require further research to confirm such utility.

Applicant's asserted utilities appear to be disclosed on pages 6-9 of the specification and include: (i) providing highly thermostable and salt-stable polypeptides (p. 6, paragraph 6), (ii) assessing the immunogenicity of the protein (pp. 6-7, paragraph bridging), (iii) comparing the protein to databases to find an indication of the function of the protein (pp. 7-8, paragraph bridging), (iv) making antibodies (p. 8, paragraphs 4-5), (v) vaccines and diagnostic reagent use (p. 6, paragraph 6), (vi) medicaments and diagnostic reagents (Id., paragraph 6), (vii) compositions that are more stable in salt and pH conditions that individual proteins (Id., paragraph 7), (viii) various processes (Id., paragraph 8), (ix) detecting proteins (p. 9, paragraph 3), and (x) detecting antibodies (p. 9, paragraph 4).

None of these utilities are specific to the protein presently claimed, and further, require further research to reasonably confirm their use, and therefore also lack a substantial utility. Specifically, nothing in the record or in the prior art indicate that this protein is specifically useful for anything but further research to reasonably confirm a possible use in the future. To wit, p. 1003 of the specification indicates that a sequence identity comparison found that the sequence is predicted to be an ATPase of the PP-loop superfamily implicated in cell cycle control. However, no other mention is provided in the specification of the function and/or structure of such protein. Still further, the Examiner has found that several other distinct proteins have similar homology to the claimed protein, but are distinct in function. For example, while a comparison between a known ATPase of the PP-loop superfamily yielded 34% homology (SEQUENCE COMPARISON 1 of 6/12/07), another protein, a thiamine biosynthesis protein (SEQUENCE COMPARISON 2 of 6/12/07) yielded 33% homology, and yet another protein, a guanine monophosphate synthetase (SEQUENCE COMPARISON 3 of 6/12/07) yielded 35% identity to the sequence of the claims. Still further, it is recognized in the Art that sequence homology does not necessarily reflect the function (e.g., Rost, et al. (2003) Cell. Mol. Life Sci., 60(12): 2637-50, p. 2638, and Goldsmith-Fischman, et al. (2003) Protein Sci., 12(9): 1813-21, pp. 1813-15). Hence, the Artisan recognizes that a simple homology between two proteins does not necessarily indicate the protein is the same as another protein, and further, the fact that several other proteins have similar homology but distinct function, indicates that the protein claimed is just as likely to have a similar function as those other proteins. Simply put, the Artisan recognizes that sequence homology indicates evolutionary relationships much more than

function. Therefore, the Artisan would have to perform further research to reasonably confirm the function of the protein, and even provide a possible utility for such protein.

In addition, Claims 4-6 and 22-23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Initially, it should be noted that, as shown in the utility rejection above, the proteins claimed have no known activity and structure associated with such, and as such, the Artisan would have to perform experimentation to determine a structure/function associated with such protein. Such experimentation is considered undue as it amounts to inventing Applicant's claimed invention for Applicant.

Further, the claims are broad for the scope of proteins encompassed. To wit, the claims are drawn to "a protein" of [the various percent identities to] SEQ ID NO: 1632, as restricted. Such is read broadly to encompass any protein with such identity to any portion of SEQ ID NO: 1632. Still further, the claims are broad for the regions of the protein which are required to have the various percent identities.

Applicant's specification discusses various utilities, as described above, and various general investigations that can be carried out to find the protein and determine what it does. Still further, the specification describes an investigation of polymerases isolated, presumably because high-temperature polymerases are commonly known in the Art to be useful for PCR protocols. However, the sole discussion at all of the protein of SEQ ID NO: 1632 is that it is "[p]redicted

[to be an] ATPase of the PP-loop superfamily implicated in cell cycle control" (SPECIFICATION, p. 1003, last row in the table). Hence, even from this disclosure the Artisan would not reasonably predict that such protein is an ATPase, but only that homology searches have shown a favorable similarity to such proteins.

On the other hand, the Art demonstrates that these PP-loop superfamily is not the only protein to which this protein has a similarity (see above, utility rejection). Still further, being a member of the PP-loop superfamily does little to identify the activity and use of such protein, as the PP-loop is generally indicative of ATPase activity, and not what the enzyme does (Deyrup, et al. J. Biol. Chem., 274(41): 28929-36). As such, even if the protein is an ATPase, it only indicates that the enzyme uses ATP in another reaction, which likely is not even its only activity, as simply cleaving ATP is not an activity carried on by cells, but the ATP is cleaved to yield energy to undergo other reactions.

Hence, because the Artisan, though being of a high level of skill, would not know the protein's activity, and even if he/she assumed it included an ATPase activity, further research would have to be carried out to determine which other activity is present in the enzyme and determine what the enzyme may do, as well as determine the regions of the various activities, and hence, the various fragments encompassed, and percent homologies, would require further experimentation. Such experimentation is considered undue because it amounts to inventing the claimed subject matter for Applicant.

Hence, the claims are not enabled.

Even though the claims are enabled, due to the extreme breadth of the claims, the following rejections are held:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-5 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Venter, et al. (2001) Science 291(5507): 1304-1351, as evidenced by SEQUENCE COMPARISON 4 of 6/12/07 and ACCESSION DATA 1 OF 6/12/07.

As noted in the enablement rejection, above, the claims encompass any protein comprising a portion with the identities listed, to SEQ ID NO: 1692.

One such protein is BAI1-associated protein 3, isoform CRA-b of humans. The attached SEQUENCE COMPARISON 4 of 6/12/07 of the first 7 amino acids of the sequence, identifies the sequence similarity to be 100%. Moreover, the sequence is first disclosed by the reference to Venter, et al., as shown in the accession data in ACCESSION DATA 1 OF 6/12/07.

Hence, the disclosed protein anticipates the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 and 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4-6 and 22-23 encompass proteins comprising sequences with various homologies to SEQ ID NO: 1692 or a generic portion thereof.

The specification only describes SEQ ID NO: 1692 as having homology to a PP-loop protein and no other description is given.

The Art in general does not describe the structure-function relation such that an Artisan would understand Applicant to have been in possession of such generic proteins. To wit, as shown above, it is not even clear to the Artisan what the protein's function is, nor is it clear which amino acids are required to obtain the function. Still further, with regard to the portions required, the Artisan would not know which portions are required to be a protein of SEQ ID NO: 1692, as shown above.

Hence, the Artisan would not have understood Applicant to have been in possession of the various homologies or portions of proteins, but only that of SEQ ID NO: 1692.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Notice to Comply	Application No. 10/506,454	Applicant(s) Slesarev	
	Examiner Robert M. Kelly	Art Unit 1633	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☒ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: Amino acid sequences listed in claims 27-28 should be identified by a sequence identifier.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
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